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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,536	02/08/2007	Donald Schomer	10988.0005-05	7815

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EXAMINER	
DOUGHERTY, SEAN PATRICK	
ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,536	SCHOMER ET AL.	
	Examiner	Art Unit	
	SEAN P. DOUGHERTY	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-56,59 and 63-67* is/are pending in the application.

4a) Of the above claim(s) *44-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-43,50-56,59 and 63-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 April 2006* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the FINAL Office action based on the 10/595536 application filed 02/08/2007.

Election/Restrictions

Claims remain 44-49 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/07/2008.

Response to Amendment

The amendment(s) filed 01/07/2010 by the Applicant in response to the previous Office action mailed 07/09/2009 have been considered by the Examiner. The Examiner acknowledges:

- Claims numbered 1-67 including:
    - Pending claim(s) 40, 41, 43-56, 59, 64-67;
    - Amended claim(s) 40, 52, 59, 63 and 67;
    - Cancelled claim(s) 1-39, 42, 57, 58 and 60-62
    - Withdrawn claim(s) 44-49.

The Applicant's amendments and/or arguments have overcome the claim objections and 35 U.S.C. 112, first paragraph rejections in the previous Office action.

The rejection(s) in the previous Office action of the claims are maintained. The following reiterated ground(s) of rejection(s) is/are set forth below:

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification fails to explicitly recite the "where the tissue engager does not extend distally beyond the tissue piecing distal tip" as set forth in claim 64.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "extend[ing] from a side of the insertion member opposite the side aperture" as set forth in claim 63 and described at paragraph 89 of the printed publication of the instant application must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40, 41, 50-56, 59, 63-67 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Where the mechanical shield is "non-inflatable" as set forth at line 5 of claim 40 is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The Examiner notes that the Applicant has not enabled a "non-inflatable" shield as set forth in claim 40. The Examiner notes any negative limitation or exclusionary proviso must have basis in the original disclosure. See In re Johnson, 558 F.2d 1008,

1019, 194 USPQ 187, 196 (CCPA 1977). The mere absence of a positive recitation is not basis for an exclusion. The "non-inflatable" limitation at claim 40 does not have basis in the original disclosure and is being rejected for failing to comply with the written description requirement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 41, 50-56, 59, 63-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation of a "non-inflatable" mechanical shield as set forth at line 5 of claim 40 renders claims 40, 41, 50-56, 59, 63-67 indefinite. The Examiner notes the Applicant discloses a mechanical shield comprising a balloon or mechanical shield that can be used to create a protective guard or barrier at paragraph 89 of the printed publication of the instant application. Specifically, the balloon and/or shield is established as being expanded via mechanical means or *inflated with air or another sterile fluid*. Therefore, the mechanical shield actually is described in the specification as being “inflatable”. Since the Applicant has not expressly disclosed a mechanical shield as “non-inflatable” (*see 35 U.S.C. 112, first paragraph rejection, above*), claim 40 is rendered indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, because the Applicant has established their invention as “inflatable”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 40, 41, 43 and 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,954,739 to Bonutti.

Regarding claims 40 and 67, Bonutti discloses a kit best seen in Fig. 6 for performing a procedure on a spine, the spine include an epidural space containing a thecal sac, the, kit comprising an insertion member (72) for accessing the epidural space, the insertion member comprising a tissue piercing distal tip (74), and non-inflatable mechanical shield (64) sized and shaped to be inserted into the epidural space by an insertion member (col. 8, ll. 18-20) and configured to be mechanically

extended (col. 7, ll. 62-64) so as to protect, compress and displace a portion of the thecal sac and provide a safety zone within the epidural space.

Note that the device of Bonutti is capable of performing a procedure on a spine. The mechanical shield is capable of being extended into any particular shape as desired for a particular application, therefore, the mechanical shield of Bonutti is capable of being extended so as to protect, compress and displace a portion of the thecal sac and provide a safety zone within the epidural space.

Note that the non-inflatable mechanical shield is non-inflatable when the balloon has reached a maximum inflation to displace a portion of the thecal sac, for instance, as best seen in Figure 6 when the balloon has met a transverse dimension 18.

Regarding claim 41, note that the insertion member of Bonutti is a cannula as devices are inserted through the insertion member for application in a working space

Regarding claim 43, Bonutti discloses an injectable medium (col. 2, ll. 33-37).

Regarding claim 63, Bonutti discloses a side aperture located in the distal side of the insertion member (72), defined by the end of the cannula. The mechanical shield extends on both sides the side aperture on opposite sides of the side aperture, as best seen in Fig. 6.

Regarding claim 64, Bonutti discloses the device best seen in Fig. 6 works as a tool. The tool includes a tissue engager (72) and a tissue cutter (74) which are capable of moving relative to each other. The tissue engager does not extend distally beyond the tissue piercing distal tip when in the position best seen in Fig. 6.

Regarding claim 65, the tissue engager (74) of Bonutti is a needle.

Regarding claim 66, note that the tissue cutter (74) is inserted into the working space by longitudinal movement through the insertion member (col. 15-18). The tissue cutter is part of the tissue piercing distal tip, therefore, they are engaged.

Claims 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,954,739 to Bonutti, as applied to claim 40 above, in view of US 5,429,136 to Milo et al. (hereinafter “Milo).

Regarding claims 50-52, Bonutti discloses an injectable medium. Bonutti does not expressly disclose where the injectable medium is an inert base radio-opaque non-ionic myelographic contrast medium.

Milo teahces a balloon lumen for introducing fluids into the lumen to inflate and deflate the balloon or to introduce other drugs and/or fluids such as radio-opaque fluids

(col. 2, ll. 35-40). Bonutti as modified by Milo discloses the claimed invention except for where the radio-opaque fluid is non-ionic and inert. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the radio-opaque fluid both non-ionic and inert, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. Such non-ionic and inert fluids would be safe for of imaging within a body in case it accidentally escapes (col. 2, lines 33-37). One having an ordinary skill in the art at the time the invention was made would have found it obvious to modify the injectable fluid of Bonutti to be the an inert base radio-opaque non-ionic myelographic contrast medium of Milo, since the predictable result of providing an imagining material within the balloon would ensue. Therefore, a skilled artisan would have found the combination of Bonutti and Milo obvious.

Claims 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,954,739 to Bonutti, as applied to claim 40 above, in view of US 7,329,402 to Unger et al. (hereinafter “Unger”, cited in IDS).

Regarding claims 53-56, Bonutti as modified discloses the claimed invention except for a bio-active agent such as a therapeutic agent such as an anti-inflammatory agent or an anesthetic steroid.

Unger teaches method of imaging and treating using target compositions (col. 1, ll. 22-26). Unger teaches bioactive agents that refer to a substance which may be used

in connection with an application that is therapeutic or diagnostic in nature, including steroids (col. 9, ll. 41-53). Bonutti as modified by Unger discloses the claimed invention except for where the therapeutic agent is an anti-inflammatory agent or an anesthetic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the therapeutic agent an anti-inflammatory agent or an anesthetic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. Anti-inflammatory agents and anesthetics are well known therapeutic agents. One having an ordinary skill in the art at the time the invention was made would have found it obvious to include the therapeutic steroids of Unger with the device of Bonutti, since the predictable result of targeting tissue for therapeutic applications would ensue. Therefore, a skilled artisan would have found the combination of Bonutti and Unger obvious.

Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,954,739 to Bonutti in view of US 5,985,320 to Edwards et al. (hereinafter "Edwards").

Regarding claim 59, Bonutti discloses a volume of medium in claim 36. Bonutti does not expressly disclose where the volume is injectable at ambient temperatures and more viscous at body temperature.

Edwards is a reference in analogous art that teaches a volume that is injectable at ambient temperatures and more viscous at body temperature. One having ordinary skill in the art at the time the invention was made would have found it obvious to modify

the injectable volume of Bonutti to include be viscous at body temperature as taught by Edwards as this modification would provide compositions and methods for enhancing intracellular delivery of bioactive agents (Edwards: col. 2, lines 6-13).

Response to Arguments

Applicant's arguments filed 01/07/2010 have been fully considered below:

Regarding the rejection of claims 40, 41, 43 and 63-67 under 35 U.S.C. 102(b), the Applicant argues at pages 6-10 that Bonutti discloses neither "a non-inflatable shield" nor a mechanical shield "sized and shaped to be inserted into the epidural space". The Examiner disagrees and respectfully submits that Bonutti does disclose a non-inflatable shield, as the non-inflatable mechanical shield is non-inflatable when the balloon has reached a maximum inflation to displace a portion of the thecal sac, for instance, as best seen in Figure 6 when the balloon has met a transverse dimension 18. Additionally, the Examiner notes that the Applicant has not enabled a “non-inflatable” shield as set forth in claim 40. The Examiner notes any negative limitation or exclusionary proviso must have basis in the original disclosure. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977). The mere absence of a positive recitation is not basis for an exclusion. The "non-inflatable" limitation at claim 40 does not have basis in the original disclosure and is being rejected for failing to comply with the written description requirement.

Furthermore, the Examiner respectfully submits that the structure of Bonutti is sized and shaped to be inserted into the epidural space. Just because the Bonutti

discloses a device that may structure that does not gently perform displacement or compression gently, does not mean that the structure is not sized and configured to be inserted into the epidural space. The size is also not a limiting factor, since the Applicant has not claimed a particular size ideal for insertion into the epidural space. All the Applicant has claimed is that the structure is adapted to be inserted into the epidural space. The device of Bonutti is at least in some manner, capable of being inserted into an epidural space. In response to Applicant's argument that the device of Bonutti is not adapted to be inserted into the epidural space, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Friday, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean P. Dougherty/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736